Published in final edited form as:

J ECT. 2008 June ; 24(2): 117–121. doi:10.1097/YCT.0b013e31815c6641.

Outcome of ECT by Race in the CORE Multi-Site Study

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Abstract

Objective—The authors examine the differences in outcome between black and white patients receiving ECT as a part of the CORE multi-site study.

Methods—A total of 624 patients were enrolled in an NIMH-funded, randomized controlled ECT trial comparing the efficacy of continuation ECT versus continuation pharmacotherapy between 1997 and 2004. This analysis focuses on the 32 black and 483 white patients who participated in phase I of the study. The authors compared baseline demographic and clinical variables, and acute outcomes of these two groups.

Results—Compared to whites, far fewer blacks participated in the study. Those who did were less likely to have failed adequate medication trials and were more likely to have psychotic features. Their initial HAMD₂₄ scores were higher than whites, and they showed a greater reduction in these HAMD₂₄ scores by the end of the treatment period. While sample size limited the statistical significance of the findings, black patients also showed a higher rate of remission after an acute phase of ECT.

Conclusions—This study found that black and white patients with major depressive disorder had comparable outcomes. We also found that fewer black patients received ECT than whites, a difference that has been reported in other samples.

Keywords

Electroconvulsive therapy; ECT; race; depression; CORE; outcome

Author Contributions: All named authors contributed equally to this publication.

Financial Disclosure: An ECT device was loaned by Somatics, Inc to Dr Kellner. Dr. Sampson has research support from Neuronetics, Inc. and organizes a CME course each year with support from Eli Lilly.

Introduction

Mental health diagnoses, psychiatric treatments, and the use of guideline-based treatments are disproportionately applied in black and white patients. National Comorbidity Survey Replication data have shown that Non-Hispanic blacks have a lower lifetime risk of mood, anxiety and substance use disorders. However, when the same group was diagnosed with anxiety or mood disorders, they were more persistently ill (1). Black patients with schizophrenia receive fewer atypical antipsychotics than whites (2). In one study, African Americans were less likely to find antidepressant medication acceptable for treating depression, less likely to believe antidepressant medications are effective, and more likely to believe that antidepressant medications are addictive than whites (3). Based on a random sample of 3,032 individuals accessed through telephone and mail surveys, blacks who successfully obtained mental health care received fewer evidence-based treatment recommendations (4).

ECT is one of the most effective treatments for patients with severe major depression with or without psychotic symptoms, yet black patients receive ECT less frequently than whites. A retrospective record review in Texas of 2267 ECT patients in the early 1990s revealed that 88.1 % were white as compared to 7.8 % black (5). Similar findings were reported in the Sample Survey Program of NIMH for 1975, 1980, and 1986 (6) in hospitals across the United States. Compared to blacks, white patients were three times more likely to receive ECT in 1980 and eleven times more likely in 1986 (6). In an analysis of a nationwide data set in 1993, black patients with recurrent major depression in 913 community hospitals were less likely than white patients to be treated with ECT (odds ratio=0.7) (7). Breakey and Dunn (8) reconfirmed this difference when comparing hospital data between 1993 and 2002 at an academic medical center. Other factors, such as age, insurance coverage, the social class of the patient, or a proxy indicator of illness severity (early readmission) did not contribute to this difference (8). This difference has also been reported outside the US in retrospective chart reviews in the United Kingdom as recently as 2006 (9).

Dawkins et al. found that black patients who received ECT were more likely than white patients to have psychotic features, and to receive medications which reduce seizure thresholds (10). Additionally, in that study the way in which ECT was administered differed between blacks and whites. Blacks were more likely to have non-standard titration procedures and consequently, apparently significantly higher seizure thresholds (10). Interestingly, the difference in seizure threshold between races disappeared when all patients received a standard titration and similar medications (10).

While these authors point out differences between ECT treatments in black and white patients, a comparison of the efficacy of ECT in these patient groups has not been reported. The present study, using data from the Consortium for Research on Electroconvulsive Therapy (CORE) Continuation ECT trial compared the response of black and white patients to ECT.

Materials and Methods

CORE carried out a multicenter, NIMH-funded, randomized controlled clinical ECT trial comparing the efficacy of continuation ECT versus continuation pharmacotherapy, between 1997 and 2004. IRB approval was obtained at all participating centers (University of Medicine and Dentistry of New Jersey-New Jersey Medical School, Medical University of South Carolina, The Zucker-Hillside Northshore-Long Island Jewish Medical Center, University of Texas Southwestern Medical Center at Dallas, and Mayo Clinic College of Medicine). Patients with unipolar major depression received an index ECT course (Phase I)

followed by randomization into one of two 6-month post-ECT relapse prevention strategies (Phase II). These consisted of either continuation ECT or a combination of nortriptyline and lithium. The study design and overall efficacy results have been published previously (11, 12).

Because of limitations of sample size in Phase II for black versus white comparisons, this paper focuses on race comparisons for the acute treatment phase (Phase I) of the study.

Subjects

Following full explanation of the procedures and written informed consent, patients with depression ages 18 to 85 years referred for ECT by their primary psychiatrist were screened for eligibility. Inclusion criteria were a diagnosis of unipolar depression with or without psychotic features, as confirmed by a Structured Clinical Interview (SCID-I) for Axis I DSM-IV Disorders (13), and a score of at least 21 on the 24-item Hamilton Rating Scale for Depression (HAMD₂₄) (14). Race was determined by consensus between the patient's self identification and the research coordinator. Exclusion criteria were a diagnosis of schizophrenia, bipolar disorder, dementia, delirium or other central nervous system disease that might affect cognition or response to treatment, substance dependence within the past 12 months, medical conditions contraindicating ECT or nortriptyline and lithium, and ECT within the three months prior to beginning the study. A total of 624 patients were enrolled in the study (i.e. received a study number). Of those, 602 patients were identified as either white or black. Out of that group, 87 patients did not meet all inclusion criteria and therefore were not entered into Phase I, leaving a total of 515 (483 white and 32 black) patients for the analysis.

Procedure

ECT procedures were standardized across all centers, using the Thymatron DGX ECT device (Somatics, Inc., Lake Bluff, IL), bilateral (bitemporal) electrode placement, dose titration to determine seizure threshold at initial treatment, and stimulus dosing at subsequent treatments of 1.5 x seizure threshold (15). Procedures for anesthesia and determination of seizure adequacy (EMG 20 sec; EEG 25) followed standardized clinical protocols compatible with current standards of care (16). Treatments were administered three times weekly in Phase I until remission occurred or a minimum of 10 ECT treatments were administered.

Efficacy Outcome

The primary instrument used to rate outcome was the HAMD₂₄ administered at baseline and before each subsequent ECT treatment in Phases I-II. For Phase I, the primary efficacy outcome was remission. Remission was declared if two consecutive HAMD₂₄ ratings were 10 with a 50% decrease from Phase I baseline.

Secondary Measurements

The modified Mini-Mental State Exam (mMMSE), with a maximum score of 57, was used as a measure of global cognitive impairment. The mMMSE has shown sensitivity to ECT-induced deficits, including recovery of functioning following ECT (17, 18). Extensive cognitive testing was performed during Phase II and will be detailed in another report.

Statistical Analysis

Demographic and clinical characteristics were compared for the two groups using pooled t-tests or the Wilcoxon rank sum test for continuous measures and χ^2 -test/Fisher's exact test for categorical measures. For primary outcome analyses in Phase I, the chi-square test was

used to compare the unadjusted proportion remitted for blacks versus whites. Logistic regression with the dichotomous outcome remitted/not remitted was used to compare remission proportions adjusted for clinical site, baseline HAMD₂₄, and age. For these analyses, dropouts were considered non remitters. Unadjusted and adjusted odds ratios (OR) and corresponding 95% confidence intervals, obtained from the logistic regression analyses, were used to describe the magnitude of the race effect. For the continuous efficacy outcome, HAMD₂₄ change from baseline, a pooled t-test was used to compare the black versus white groups. A general linear models approach was used to compare the mean HAMD₂₄ change scores adjusted for age, baseline HAMD₂₄, and clinical site.

For the hypothesis testing component of these analyses (i.e., the reporting of p-values), failure to detect a statistically significant racial difference may be due to low power of the statistical test resulting from the small number of blacks in the sample. Significance was set at a p-value of < 0.05. For this reason, results should be considered descriptive and hypothesis generating rather than hypothesis confirming.

Results

Patient demographics

Of the enrolled sample of 515 patients entering the acute phase (Phase I), 483 (93.8%) were white, and 32 (6.2%) were black. 87 patients were given a study number, but did not meet inclusion criteria to enter phase I, of whom 80 (92%) were white, and 7 (8%) were black. Demographic differences of enrolled patients are illustrated in Table 1.

In a comparison of the Phase I sample of 515 patients who participated in Phase I with those 87 patients who received a study number, but did not meet inclusion criteria, no statistically significant differences were found other than in regards to educational level. The group that did not enroll as a whole (blacks and whites) was less educated ($p = 0.011$). The number of non-enrolled blacks was too small to explore this comparison further.

Baseline clinical characteristics

Clinical comparisons of the two groups as they entered phase I are shown in Table 2. Psychosis was found at a rate of 59.4% among blacks, compared to 27.1% among whites ($p = 0.0001$). Blacks had fewer prior episodes of depression, and were less medication resistant as defined by the ATHF (19) ($p = 0.009$). The age of onset of first psychiatric illness and the length of the current episode were not significantly different in the two groups. Relative to white patients, black patients were found to have significantly lower total scores on the MMMSE and significantly higher HAMD₂₄ total scores at baseline. No statistically significant racial differences in mean GAF scores or in seizure threshold were observed.

Acute ECT (Phase I) efficacy outcomes

For the total sample of 515 black and white patients who entered the acute ECT phase of the study, 63.4% (306/483) of white MDD patients remitted compared to 71.9% (23/32) of black MDD patients (Table 3). Although not statistically significant, the unadjusted odds ratio for the racial comparison was 1.5, indicating that the odds of remitting for blacks was 1.5 times higher than that for whites (95% CI for OR: 0.7, 3.3, $p = 0.333$). Adjustment for age, baseline HAMD₂₄, psychosis, and clinical site did not appreciably affect the magnitude of the association (adjusted OR: 1.5; 95% CI: 0.7, 3.5, $p = 0.300$). The unadjusted and adjusted 95% CI's indicate that, with 95% confidence, the odds of remitting could range from 3.5 times higher to 0.7 times lower for blacks compared to whites.

For the continuous efficacy outcome, blacks had an average HAMD₂₄ total score of 10.5 (± 8.9) at the end of the acute phase compared to 11.4 (± 9.1) for white patients. Black patients improved from baseline, on average by 3.7 points more than white patients ($p=0.057$). The 95% CI for difference in change scores for blacks compared to whites ($-0.1, 7.5$) suggests that blacks may exhibit mean change scores that range from 0.1 units inferior to whites to 7.5 units superior to whites. Following adjustment for age, HAMD₂₄, and clinical site, the difference in change scores was 1.7 (95% CI: $-1.5, 4.9$ $p=0.303$). The nonsignificant association following addition of baseline HAMD₂₄ to the model (containing age and site) suggests that the more severe disease among blacks at the outset of treatment is a possible explanation of their larger mean change in HAMD total scores following acute ECT. It should be noted that the 95% CI for the adjusted change scores indicates that mean improvement in blacks ranges from 1.5 units inferior to whites to 4.9 units superior to whites. Addition of psychosis to the model containing age, clinical center, and age did not appreciably alter the relationship between race and outcome (95% CI on change scores: $-1.9, 4.7$, $p=0.398$).

Discussion

Several studies have identified the disparity between blacks and whites receiving ECT (5–8). To our knowledge, this is the first study to examine the outcome differences between black and white patients receiving ECT. Similar to previous reports, fewer blacks were referred for ECT and therefore fewer blacks were eligible to participate in ECT related research. Without data on the absolute percentages of blacks versus whites in the population from which these patients were drawn at each of the sites, we cannot know for certain to what extent the smaller number is a representative or disproportionate sample. For this and other reasons, this paper does not try to address the many reasons why fewer blacks might have been referred for ECT. Among those who were referred, blacks were more likely to be psychotic and less likely to have failed adequate medication trials than whites, and had experienced fewer episodes of depression. Blacks did not have a difference in seizure threshold in this study, although such a difference has been reported elsewhere (9, 20). Although fewer black patients received ECT, those who did had outcomes comparable to white patients.

Our sample showed a higher rate of psychosis and higher initial HAMD₂₄ scores in black patients. Psychosis and depression severity have been associated with better ECT outcomes (21), and this might explain the slightly higher rate of remission in blacks. Blacks had fewer prior episodes of depression, and were less medication resistant on study entry. This may be because the most ill patients often bypass medication trials to receive ECT. Blacks in this study had lower levels of education and were more frequently unemployed. The literature describes a lower acceptance by blacks of antidepressants prior to the initiation of ECT (3) which may reflect decreased access to ongoing healthcare.

This study is limited by the fact that it was not specifically designed to compare outcomes in ECT patients by race. Therefore, as is true of all post-hoc analyses, comparisons may be biased. Data were not collected that would allow further exploration of the differences between black and white populations in psychiatric diagnoses, treatment, and in research participation. The labels, black and white, were identified through consensus between the patient and the research examiner. These terms are imprecise and there is much heterogeneity in the groups, both factors which may complicate any conclusions. In addition, there was insufficient power to explore differences in remission and relapse rates, particularly in those who entered phase II of the study.

Conclusions

We found no statistical evidence to indicate that the outcome of acute ECT in blacks was either inferior or superior to that in whites. We observed a trend towards higher ECT remission rates and greater improvement in HAMD₂₄ scores among black patients. However, this trend may be explained by racial differences in this sample in the baseline severity of depression and/or differences in psychosis status. This report highlights the importance of offering and encouraging treatments such as ECT to all patients who have severe depressive symptoms.

Acknowledgments

Funding/Support: This study was supported by National Institute of Mental Health grants MH55484 from the Mayo Foundation; MH55486 from The Zucker Hillside Hospital, North Shore–Long Island Health System; MH55489 from the University of Texas Southwestern Medical Center at Dallas; MH55485 from the Medical University of South Carolina; and MH55495 from the University of Medicine and Dentistry of New Jersey–New Jersey Medical School.

A special acknowledgment goes to Harold Sackeim, PhD, and A. John Rush, MD, for their contributions to the design and conduct of this study. We also thank the study team: Linda Akers, Samuel H. Bailine, MD, Mark Beale, MD, Hilary J. Bernstein, DHA, Barbara Bettini, Melanie Biggs, PhD, John Black, MD, Beata Boudoin, PhD, Raphael Braga, MD, Stephen Bryant, MD, Carol Burns, RN, Irene Carasiti, RN, C. Munro Cullum, PhD, Donna Felmlie Devine, Michael Downing, MD, Dina Drubach, Karen Graszner, Julie Hathaway, MS, David Hernandez, Kelly Jacobson, Mark Little, MD, Anna Lucatorto, Chitra Malur, MD, Donald McAlpine, MD, Shawn McClintock, MS, Joanne McCormack, CSW, Monica Mendez, Madelyn Myers, RN, Paul Orsulak, PhD, Lisa Perdue, MD, Kemuel Philbrick, MD, Christopher Phillips, RN, Jarret Richardson, MD, Judy Shaw, Sorina Simion-Rodgers, MD, Margaret A. Sinex, Karen Snyder, Diane Stegman, RN, Bruce Sutor, MD, Christine Svetina, PhD, Larry Thornton, MD, Kristen Tobias, Eusil Yim, MS, and Wenle Zhao, PhD.

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Table 1

Demographic Characteristics of White and Black MDD Patients

Variable	White (n=483)	Black (n=32)	p-value
Age (mean±sd)	55.8 ± 16.7	51.3 ± 15.7	0.147 ¹
Gender			0.211 ²
%Female	67.5% (326/483)	78.1% (25/32)	
Marital status			0.549 ²
Single	15.2% (73/480)	21.9% (7/32)	
Married	51.0% (245/480)	46.9% (15/32)	
Sep/Divorced	19.6% (94/480)	15.6% (5/32)	
Widowed	14.2% (68/480)	15.6% (5/32)	
Living situation			0.283 ²
Alone	26.2% (120/488)	20.0% (6/30)	
With family/roommate	68.6% (314/488)	80.0% (24/30)	
Other	7.9% (36/458)	0%	
Highest education attained			0.046 ²
Not high school grad	15.9% (71/447)	33.3% (10/30)	
High school grad	24.2% (108/447)	16.7% (5/30)	
At least some college	60.0% (268/447)	50.0% (15/30)	
Work situation			0.034 ²
Employed	34.8% (157/451)	20.7% (6/29)	
Unemployed	15.3% (69/451)	27.6% (8/29)	
Retired	35.9% (162/451)	24.1% (7/29)	
Other	14.0% (63/451)	27.6% (8/29)	

¹ p-value from pooled t-test;² p-value from chi-square test

Table 2

Comparison of Baseline Clinical Characteristics of White and Black MDD patients *

Variable	White (n=483)	Black (n=32)	P-value
Psychotic (%)	27.1% (131/483)	59.4% (19/32)	0.0001 ²
Med. Resistant (%) **	54.1% (167/309)	15.4% (2/13)	0.009 ²
Number of prior episodes	2.4 ± 4.0	1.4 ± 2.3	0.043 ¹
Age at onset of 1 st psych illness	38.0 ± 20.0	38.3 ± 19.1	0.938 ¹
Length of current episode	49.3 ± 81.7	46.4 ± 48.4	0.584 ³
HamD ₂₄ BL Ph 1	35.2 ± 7.1	37.9 ± 6.1	0.033 ¹
mMMSE BL Ph 1	48.0 ± 6.6	39.7 ± 10.5	0.001 ¹
GAF BL Ph 1	36.9 ± 11.5	35.9 ± 10.3	0.638 ¹
Seizure threshold (excluding titration violators) phase I	(n=470) 25.2 ± 14.1	(n=31) 26.6 ± 17.6	0.587

* categorical variables presented as percentages; continuous variables presented as mean±standard deviation;

** smaller number due to missing data

¹ p-value from pooled t-test;

² p-value from chi-square test;

³ Wilcoxon two sample test

Table 3

Comparison of Acute ECT Outcome of White and Black MDD Patients

	White (n=483)	Black (n=32)	OR ¹ 95% CI ²	OR ³ 95% CI ²
Categorical outcomes				
% remitters (95% CI)	63.4% (306/483) (59.1, 67.7)	71.9% (23/32) (56.3, 87.5)	1.5 (0.7, 3.3)	1.5 (0.7, 3.5)
% dropouts	26.7% (129/483) (22.8, 30.6)	18.8% (6/32) (5.3, 32.3)	0.6 (0.3, 1.5)	
Continuous outcomes				
			Difference ⁴	
			(95% CI) ⁵ p-value	(95% CI) ⁶ p-value
HAMD ₂₄ final	11.4 (±9.1) (10.6, 12.2)	10.5 (±8.9) (7.3, 13.7)	-1.0 (-4.2, 2.3) 0.566	-1.4 (-4.7, 1.9) 0.398
HAMD ₂₄ change from baseline	23.7 (±10.7) (22.8, 24.7)	27.5 (±9.9) (23.9, 31.0)	3.7 (-0.1, 7.5) 0.057	1.4 (-1.9, 4.7) 0.398

¹ OR=odds ratio. The unadjusted OR is interpreted as the odds of a given outcome for blacks compared to whites, e.g. the odds of remitting for blacks are 1.5 times higher than the odds of remitting for whites.

² 95% CI that do not contain the null value of 1 indicate a statistically significant result at the 5% level of significance. For 95% CI containing the null value 1, the results cannot be deemed statistically significant at the 5% level of significance (p>0.05)

³ Adjusted OR obtained from logistic model containing age, clinical site, baseline HAMD₂₄, and psychosis status. The adjusted OR is interpreted as the odds of remitting for blacks compared to whites after adjustment for age, clinical site, baseline HAMD₂₄, and psychosis status.

⁴ Subtraction is blacks minus whites. For HAMD₂₄ final, a negative number indicates lower HAMD₂₄ mean for blacks; for HAMD₂₄ change from baseline a positive value indicates greater changes from baseline for blacks.

⁵ Unadjusted differences in means. p-value obtained from pooled t-test.

⁶ Adjusted differences in means. p-value and 95% CI obtained from general linear model containing race as the primary independent variable and age, clinical site, baseline HAMD₂₄, and psychosis status as covariables. The means (and CIs) in the final columns represent the differences in least squares means obtained from the glm.